

REMARKS

This communication is submitted in response to the Office Action dated November 9, 2004.

Claims 1, 7 and 9-11 are pending in the subject application.

The specification has been amended to update the status of the parent applications identified in the cross-reference to related patent applications and to correct several grammatical inconsistencies. As requested by the Examiner, the specification has also been amended to supply the proper trademark designation for "C-Flex™".

Reconsideration of the subject application is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1 and 9-11 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,406,453. Claim 7 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,406,453 in view of Morris. Claim 1 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,692,455. Claim 7 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,692,455 in view of Morris.

All of the foregoing double patenting rejections are submitted to be overcome by the terminal disclaimer filed herewith with the requisite terminal disclaimer fee and disclaiming the terminal part of the statutory term of any patent granted on the subject

application which would extend beyond the expiration dates of U.S. Patents No. 6,406,453 and No. 6,692,455.

The rejection of claim 1 as being unpatentable over Shikani and the rejection of claim 7 as being unpatentable over Shikani in view of Morris are respectfully traversed for the following reasons.

Independent claim 1 recites “a hollow tubular shaft having a distal end for placement in the anatomical structure and a passage formed therethrough, said hollow tubular shaft being made of a first material having a rigidity to resist bending and maintain said passage in an open condition when said distal end is placed in the anatomical structure; and a flange extending outwardly from said distal end of said hollow tubular shaft, said flange being made of a second material having a rigidity sufficiently less than that of said first material to permit said flange to deform in response to contact with the anatomical structure during placement of said distal end in and removal of said distal end from the anatomical structure.” Shikani fails to provide any teachings or suggestions by which independent claim 1 can properly be considered obvious. Shikani discloses a ventilation tube 10 comprising a central tubular section 12, a rectangular flange 22 fitted onto the proximal end 14 of tubular section 12, and a triangular flange 34 fitted onto the distal end 16 of the tubular section 12. The tubular section 12 has a lumen 18 which extends through both flanges 22 and 34. Shikani explicitly discloses that the entire ventilation tube 10, i.e. tubular section 12 and flanges 22 and 34, is molded from elastomeric material (column 3, lines 26-27) and, in particular, from a flexible elastomeric material (column 3, lines 56-67). Accordingly, the explicit teachings of Shikani are limited to the tubular section 12 and the flanges 22 and

34 all being made of one and the same flexible elastomeric material. This limitation is reflected in independent claim 1, the sole independent claim of the Shikani patent, which recites a flexible vent member (tubular section 12), a first rectangular flexible flange member (flange 22) and a second triangular flexible flange member (flange 34). Shikani discloses an alternative embodiment where the entire ventilation tube 10 is made of higher durometer material than silastic. Where the entire ventilation tube 10 is made of higher durometer material than silastic, grooves 54,56 are etched in flange 34 to assist in bending the corners of flange 34 against the tubular section 12 for insertion of flange 34 through an antrostomy opening. Regardless of whether the entire ventilation tube 10 is made of silastic or, alternatively, a higher durometer material than silastic, there are no teachings or suggestions whatsoever in Shikani of the tubular section 12 being made of a material having a rigidity to resist bending and of the flange 34 being made of a material having a rigidity less than that of the tubular section 12 to permit the flange to deform in response to contact with anatomical structure. As pointed out above, the explicit teachings of Shikani are limited to the entire ventilation tube being formed of one and the same material of the same durometer.

The Examiner equates flange 22 of Shikani with the flange recited in independent claim 1. However, flange 22 is fitted onto the proximal end 14 of tubular section 12 and not on the distal end 16 of tubular section 12 which is placed in the antrostomy opening. Flange 22 of Shikani thusly does not properly correspond to the flange recited in independent claim 1 which is required to extend outwardly from the distal end of the tubular shaft placed in the anatomical structure. The Examiner relies on Fig. 2 of Shikani as teaching that the material of flange 22 is more flexible than the

material of tubular section 12. The Examiner's interpretation of Fig. 2 of Shikani and the teachings derived by the Examiner therefrom are respectfully submitted to be clearly erroneous. Shikani explicitly describes Fig. 2 as disclosing the ventilation tube 10 when the rectangular flange 22 is forcefully grasped and folded over with a hemostat or forceps (not shown in the drawing) (column 3, lines 52-60 and column 4, lines 19-34). Since Fig. 2 of Shikani depicts only the flange 22 being forcefully grasped and folded via an instrument, it provides no teachings or suggestions whatsoever with respect to the flexibility of flange 22 relative to tubular section 12, which is not forcefully grasped and folded with an instrument in Fig. 2. Indeed, the Examiner's interpretation of Fig. 2 contradicts the essential literal teachings of Shikani that the entire ventilation tube is made of one and the same material and that the tubular section 12 and both flanges 22 and 34 are all flexible, with none being more or less flexible than the other.

The Examiner refers to column 4 of Shikani as teaching that the drain tube and T-body may be made of different durometers. It is not seen where in column 4 the Examiner has found the teaching of a drain tube and T-body of different durometers, and it is respectfully requested that the Examiner identify the particular statements relied on in column 4. If the Examiner's reliance is based on the alternative embodiment described in column 4 and illustrated in Figs. 5 and 6 of Shikani, it should be noted as pointed out above that the description provided by Shikani for this alternative embodiment does not teach or suggest that the tubular section 12 and either flange 22 or 34 have different durometers but only that grooves are provided in flange 34 where the entire ventilation tube is made of a higher durometer material than silastic.

In light of the foregoing, independent claim 1 can only be considered obvious over Shikani by reconstructing the ventilation tube of Shikani in a manner departing from the explicit teachings of Shikani and relying on impermissible hindsight made possible only with the teachings of applicant's invention. Accordingly, independent claim 1 is submitted to be clearly patentable over Shikani and should be allowed along with dependent claims 7 and 9-11.

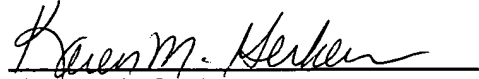
Claim 7 depends from claim 1 and recites "said first material is a metal and said second material is a polymer." Claim 7 stands improperly rejected as being unpatentable over Shikani in view of Morris. Morris fails to teach or suggest the features recited in claim 7 and also fails to rectify the deficiencies of Shikani with respect to independent claim 1. Morris discloses a tubular medical device 10 comprising a body member 28 and rib structure 30 connected to and projecting outwardly from an outer surface 32 of body member 28. Figs. 5a, 5b and 10 of Morris depict tubular medical devices placed in anatomical structures, and it is clearly illustrated in Figs. 5a, 5b and 10 that the rib structures are not deformed in response to natural forces N or extrusion forces E acting on the tubular medical devices. Accordingly, there are absolutely no teachings or suggestions whatsoever by Morris of the rib structures being made of a material having a rigidity less than that of the material from which the body member is made. Indeed, an essential feature of the tubular medical devices disclosed by Morris is that the rib structures not be deformable; and, notably, Figs. 5a, 5b and 10 show that the anatomical structures deform around the rib structures without the rib structures being deformed by the anatomical structures. Fig. 5b depicts removal of the tubular medical device 10 from the anatomical structure and

demonstrates that the rib structure, unlike the flange recited in claim 1, is not deformed in response to contact with the anatomical structure during removal. Morris discloses that the body member and the rib structure are fabricated from either a stiff yet resilient material such as rubber, plastic, silicone and polyethylene or a rigid material such as stainless steel and titanium (column 2, line 67-column 3, line 3). Morris further states that it is possible for the body member and rib structure to be fabricated from the same material or different materials (column 4, lines 49-56). However, in view of the teachings by Morris that the rib structure not deform in response to contact with the anatomical structure during removal of the tubular medical device from the anatomical structure and that the anatomical structure in fact be deformed by the rib structure, the mere mention by Morris of the possibility of different materials for the body member and rib structure cannot be interpreted as constituting a teaching that the rib structure be made of a material less rigid than the material of the body member, let alone sufficiently less rigid to deform in response to contact with the anatomical structure during placement in and removal from the anatomical structure. Accordingly, Morris fails to provide any teachings or suggestions with respect to the specific features recited in claim 7 and does not rectify the deficiencies of Shikani with respect to independent claim 1. Dependent claim 7 is thusly submitted to be clearly patentable over Shikani in view of Morris for the additional limitations recited therein as well as being allowable with claim 1.

In light of the foregoing, all of the claims in the subject application are submitted to be in condition for allowance. Action in conformance therewith is courteously solicited. Should any issues in the subject application remain unresolved, the Examiner

is encouraged to contact the undersigned attorney.

Respectfully submitted,


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